

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-2213]

*DMB*

Display Date	<i>7-10-01</i>
Publication Date	<i>7-14-01</i>
Certifier	<i>LAJ</i>

**Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors" dated July 2001. The guidance document provides guidance to blood establishments on when to invalidate donor test results based on control reagents required by the Clinical Laboratory Improvement Act of 1988 (CLIA). The implementation of additional quality control procedures that involve the use of external control reagents should enhance overall testing accuracy and blood safety. The guidance document announced in this notice finalizes the draft guidance document entitled "Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors" dated September 1999.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors" to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research

(CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

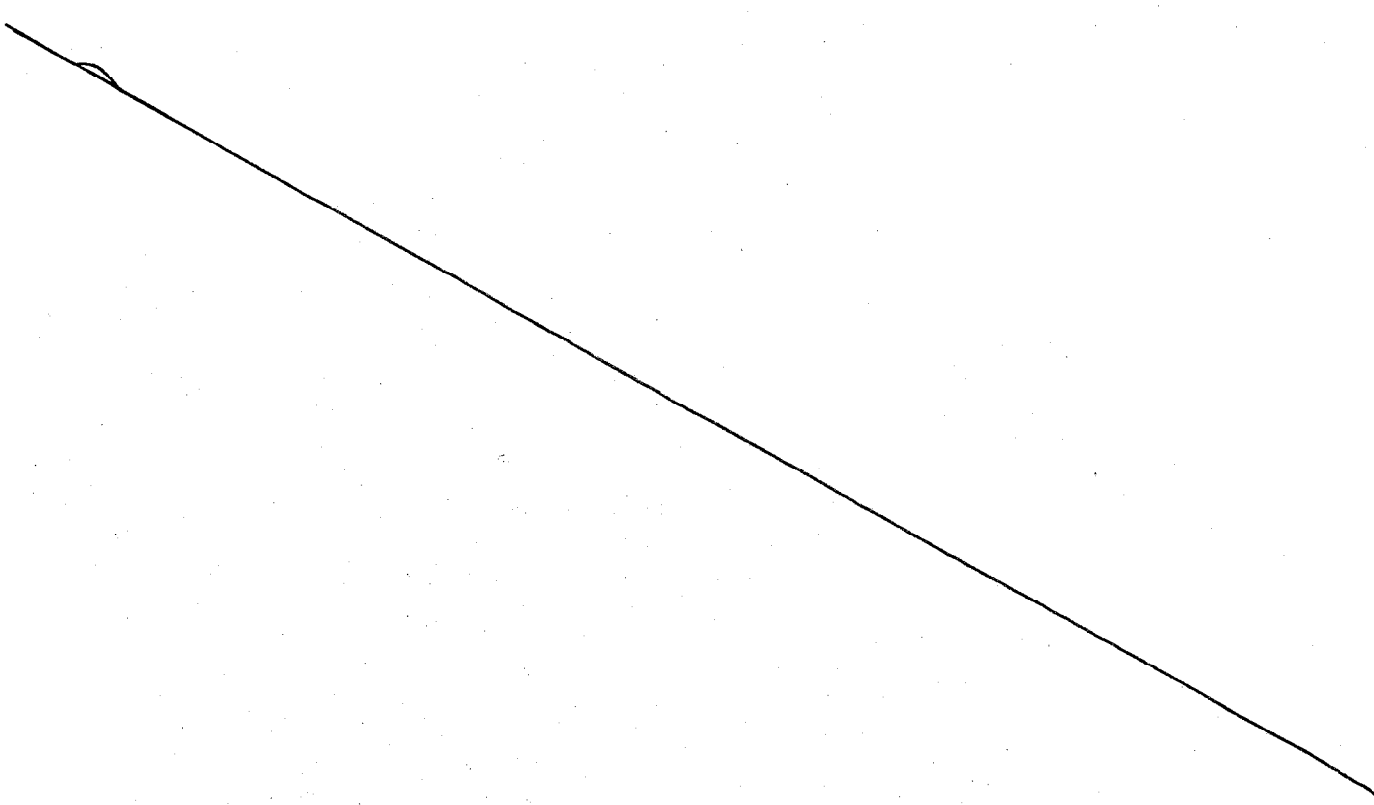
FDA is announcing the availability of a guidance document entitled "Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors" dated July 2001. The guidance document provides recommendations for blood establishments in integrating current CLIA requirements for when to invalidate donor test results based on CLIA required control reagents. The guidance document announced in this notice finalizes the draft guidance document entitled "Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors" announced in the **Federal Register** of September 1, 1999 (64 FR 47847). The guidance document also supersedes the January 3, 1994 guidance document entitled "Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors."

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's

current thinking with regard to the invalidation of test results based on the CLIA required control reagents. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

## **II. Comments**

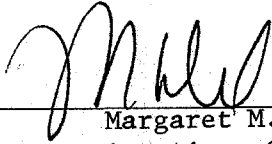
Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of this guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



### III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>

Dated: 6/27/01  
June 27, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE  
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[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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